DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DUST EXTRACTION UNIT

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1.0 Pre-approval Protocol:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

Functional area	Name	Designation	Signature	Date
PREPARED BY				
User Department				
REVIEWED BY				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

2.0 OBJECTIVE: To prepare the detailed specification (Design data) for all major components of the equipment / system to ensure that the user requirement specification and Functional requirement specification or data sheet are achieved.

To design the equipment/ system in conjunction with the design data in order to provide basis for the vendor, manufacturer the design engineer for designing the system when the project begins.

3.0 SCOPE: The scope of this Design Qualification is that **"Dust Extraction Unit Capacity: 180 CFM"** is designed and manufactured according to specified/ required standards and regulation.

4.0 Reason for DQ: To procure Dust extraction unit of 180 CFM capacity to be installed in Block-1 for extraction of dust from the tablet press during production and to keep the compression zone of tablet press clean.

The reason for preparing this document is:

Please tick any one (or multiple) option(s) from the following (☑):

Refurbished premises/equipment	☐	
Purchase of Utility Systems		☐
Purchase of Process Equipment	☑	
Purchase of Laboratory Equipment		☐
Bespoke or user configured computer systems	☐	
In-Use Systems that don't have a URS	☐	
Others (Specify)		☐

5.0 Refer attached Manufacturer/Supplier Design Qualification No. (if applicable):

Refer attached DQ No.:_____.

6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare, evaluate the design parameters with respect to User Requirement Specification (URS), Functional design specification, cGMP requirement and record the information
Engineering		To verify the utilities, certify components, location and equipment parameters
Health Safety and Environment		To verify and provide the safety requirements of equipment and facility
Quality Assurance		To be a part of team and review the documents
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document

7.0 Equipment Description:

Dust Extractor deals with the process to extract the dust from the tablet press during production and keep the compression zone of tablet press clean.

Dust laden air is sucked by a Vortex pump and enters in the filter housing through a suction adaptor, where dust laden air is deflected around filter bag by deflector. Deflected air is sucked by pressure and pass through fine filter bag. The dust particles stuck to the inner wall of the filter housing and outer face of the filter bag. The Dust laden air passes upward through filter bag. The Top of filter cage with filter bag is mounted with highly effective spring action shaking mechanism, operated by a shaking knob on top of the filter housing assembly. On operating the shaking mechanism, the dust deposited on the outer wall of the filter bag is dropped into filter housing. The high level vortex pump is suck the dust laden air through filter bag, then cleaned discharge air in atmosphere after filtered by

exhaust filter. Castor wheels are fitted at bottom side of the machine to give complete manoeuvrability.

8.0 Information of Input Material: The input material will be dust/ powder from the tablet press during compression of tablets.

9.0 Information of Output Material: The output material will be extracted dust/ powder.

10.0 Environment: This section gives a brief summary of the layout and physical condition of the proposed site of the equipment. This includes (but not limited to), the data sheet of the room where proposed equipment is to be placed with proposed placement drawing showing room dimensions, door/window locations and dimensions, etc.

S.No.	Parameter	Acceptance criteria (based on FDS / technical discussion)	Observation	Remark
1.	Available area	Area (4.6 m Length x 4.5 m Breadth x 4.5 m Height)		
		Area grade/class: ISO 8		
		As Built Area Layout attached as attachment No._____		
		Should be able to accommodate in Compression area		
		Should be installed at the suitable area for ease in cleaning		
2.	Maximum Expected size of equipment (approx.)	NMT 80 mm Width x 108 mm dia. x 155 mm Height		

11.0 Equipment Design and Principle of Working: NA

12.0 Process Description:

Pump of the dust extractor sucks the dust from the tablet press. The dust laden air enters in the filter housing through a suction adaptor. The dust laden air is deflected around the filter bag by deflector. Deflected air is sucked by pressure and pass through fine filter bag. The duct particles stuck in the inner and outer wall of the filter bag. The cleaned air is discharged in to the atmosphere after filtered by exhaust filter.

13.0 Functional Requirements of Equipment:

13.1 Functionality of the Equipment: The desired functional requirements and how it operates are listed under this section.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Use / Purpose	The equipment should be able for extraction of dust particles generated during the compression of granules.		
2.	Capacity / Working Capacity	180 CFM		
3.	Model	cGMP		
4.	Dust storage capacity	➢ Up to 10 liters		
5.	Vacuum pump	➢ Shall be provided		
6.	Vacuum suction nozzle	➢ Shall be provided at rear end of the machine		
7.	Filter bags	➢ Shall be provided with in the working zone		
8.	Filter housing	➢ Shall be provided below the filter bag.		
9.	Shaking knob assembly	➢ Shall be provided on the top side of filter housing		
10.	Cover on filter housing	➢ Shall be provided		
11.	Inlet adaptor	➢ Shall be provided		
12.	Deflector	➢ Shall be provided		
13.	Cage for filter bag	➢ Shall be provided		
14.	Silicone ring	➢ Shall be provided		
15.	Vacuum Blower	➢ 2.2 Kw, 380-420 V, 50 Hz		
16.	Motor	➢ 2.25 Kw, 380-420 V, 50 Hz		

13.2 Instrumentation Requirements: This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters. e.g. RPM indicator, pressure gauge, flow meter, printer etc.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
NA				

13.3 Data Collection and Reporting: This section mentions in brief the data that is expected from the equipment with the respective unit of measurement. Need for printouts is also mentioned, if applicable e.g. temperature, RPM, pressure, etc.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
NA				

13.4 Recipe Provision / Data saving / Data Back-up / Data Security: This section specifies the requirements (as applicable) for recipe provision, data saving facility, data back-up facility, data security facilities, etc.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
NA				

13.5 Performance Features: Mention in brief the performance requirements; the parameters that are planned to be evaluated during performance qualification and process validation activities are mentioned.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Performance of the machine according to operation.	The machine is intended to be operated regularly: 24 hours, 7 days per week with cleaning in between batch/ product changeover.		
2.	Change over time	A minimum change part to reduce the product change over time is required.		
3.	Cleaning Requirements	Easy accessible for cleaning. Parts which are required for cleaning should be provided with quick fixing arrangement.		

13.6 Capacity / Speed: The desired capacity/speed with the UOM is specified in this section.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Capacity	180 CFM		

13.7 Automation and Safety Features: The minimum required as well as desired automation and safety features (alarms, interlocking, etc.) are listed in this section. e.g. for loading/unloading/material handling/ WIP activities, etc.

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
NA				

13.8 System Boundaries: Nil.

13.9 Material of Construction: Specifications for material of construction of contact parts, non-contact parts, etc. are listed here.

S.No.	Parameter	Specifications/Dimension	Observation	Remark
1.	Filter housing	➢ SS 316L		
2.	Cover on Filter housing	➢ SS 316L		
3.	Inlet adaptor	➢ SS 316L		
4.	Deflector	➢ SS 316L		
5.	Cage for filter bag	➢ SS 316L		
6.	Non contact parts	➢ SS 304		
7.	Filter	➢ SS 316		

13.10 Surface Finish: Specifications for surface finish of contact parts, non-contact parts, etc. are listed here.

S.No.	Parameter	Specifications/Dimension	Observation	Remark
1.	Internal Surface finish (Product contact parts)	Smooth and Mirror polished inside surface with no welding burrs and crevices. Corners shall be rounded		
2.	Outer Surface finish	Dull polished.		

13.11 Electrical and Control Equipment Philosophy: A brief detail of the control requirements and whether the equipment is to be controlled using electrical system/ microprocessor/ PLC/ computers or a combination of these are mentioned in this section.

S.No.	Parameter	Specifications/Dimension	Observation	Remark
NA				

13.12 cGxP Considerations: The requirements for electronic compliance of the equipment.

S.No.	Parameter	Specifications/Dimension	Observation	Remark
NA				

14.0 Expected Documents and Drawings: Requirement of documents to be delivered by the suppliers during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

S.No.	Document details	Required (✓ / ✗)
1.	Design Specifications	☑
2.	Functional Specifications	☒
3.	PLC Alarm/Interlock/Safety/ communication/power failure test procedures	☒
4.	Piping and Instrumentation Diagram (P&ID)	☒
5.	Instrument Listing	☒
6.	Control Schematics	☒
7.	Control Panel Assembly Drawings	☒

S.No.	Document details	Required (✓ / ×)
8.	Machine Assembly Drawings	☒
9.	Bill of Materials	☒
10.	Operator, Maintenance and Service Manuals	☑
11.	Spare Parts List	☑
12.	MOC certificates	☑
13.	Calibration certificates of instruments	☒
14.	Test certificates of components/test devices	☒
15.	Weld certificates (if any)	☒
16.	'As-built' P&ID	☒
17.	GA drawing	☑
18.	Isometric drawing (if any)	☒
19.	Electrical drawings	☑
20.	Component Cut Sheets (optional)	☒
21.	PLC Program Printouts and Disk File (optional)	☒
22.	HMI Configuration Printout and Disk File (optional)	☒
23.	Other (Specify)	☒

✓: Applicable & required × : Not applicable

15.0 Available Utilities:

S.No.	Parameter	Specifications/Dimension	Observation	Remark
1.	Electricity	Electrical supply three Phase		
		Frequency: 50 Hz		
		Voltage: 415 volts		

16.0 Maintenance Requirements: Maintenance related requirements like accessibility for easy maintenance, required spares, etc. are listed here.

S.No.	Parameter	Specifications/Dimension	Observation	Remark
1.	Maintenance	Easy accessibility for maintenance		
2.	Spare parts	List of spare parts and spare parts should be provided		

17.0 Delivery, Installation and Commissioning Requirements:

17.1 Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/ supplier service engineer.

17.2 Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.

17.3 FAT if any required by the customer then, same to be performed jointly by the nominated persons from both the side at the manufacturer's site.

17.4 The manufacturer should install, qualify and commission the equipment at the user site and provide the necessary training to the user for operation and cleaning. Training to be provided by the manufacturer for the necessary critical steps involved in the operation, cleaning, maintenance, safety and handling of equipment.

18.0 Other Specific Requirements: To provide the necessary servicing at the site at defined intervals. Language requirements in manual should be in English.

19.0 Reference Documents: Nil.

20.0 Abbreviations: Full forms of all abbreviations are listed here.

Abbreviation		Full form
cGMP	:	Current Good Manufacturing Practice
GEP	:	Good electrical practices
ISO	:	International Standard Organization
L	:	Litre
MOC	:	Material of Construction
L x B x H	:	Length x Breadth x Height
Sr. No.	:	Serial Number
SS	:	Stainless Steel
URS	:	User Requirement Specification
dia.	:	Diameter
FAT	:	Factory acceptance test
DQ	:	Design Qualification

21.0 Attachments: This section contains a list of all attachments referenced in the protocol.

S.No.	Attachment Details	Attachment No.

22.0 Recommendations/Conclusion :

23.0 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PERFORMED BY				
User Department				
Engineering				
EHS				
Quality Control (if applicable)				
Validation QA				
REVIEWED BY				
User Dept. Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				